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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,427	02/18/2004	John F. Ziobro	AT-119US	3478

24314 7590 01/19/2006

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EXAMINER	
KRAMER, NICOLE R	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

TJW

Office Action Summary	Application No.	Applicant(s)
	10/781,427	ZIOBRO ET AL.
	Examiner	Art Unit
	Nicole R. Kramer	3762

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/24/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: detecting electromyographic events in response to the applied stimulation and utilizing the detected electromyographic detection events to map the cortex.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-37 and 40-42 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2004/0158298 ("Gliner et al.").

Gliner et al. discloses a system (system 100) comprising a plurality of subdural electrodes formed as a grid (electrode array 110 can be a grid having a plurality of

discreet electrodes 114 arranged in an X-Y coordinate system; see paragraph 0023. The electrode array can be a cortical neural-stimulation device in which the electrodes are placed generally over or proximate to a target location such as the surface of the cortex for stimulation; see paragraphs 0025 and 0045); a cortical stimulator for stimulating individual pairs of the plurality of subdural electrodes (stimulus unit 120 includes a pulse system 140 for generating and sending energy pulses to the electrode array as described in paragraph 0024); and an electromyograph for detecting reaction to the stimulating (sensing deice 180 is operatively coupled to the stimulus unit 120; see paragraph 0022. The sensing device 180 may be an any suitable apparatus for determining a response in the patient to a stimulus applied to the electrode array as described in paragraph 0026. Gliner et al. discloses that the sensing device 180 can be an EMG device; see, for example, paragraphs 0033-0034).

With respect to claims 2 and 17, Gliner et al. discloses a controller structured for associating the reaction with one of the individual pairs of the plurality of subdural electrodes (stimulus unit 120 includes a controller 130 which sends command signals to the pulse system 140 defining the configuration of active electrodes and waveform parameters for the stimulus, and receives signals corresponding to the magnitude of the responses from the sensing device 180 as described in paragraph 0027. The controller associates the reaction with one of the individual pairs of the plurality of subdural electrodes in that the controller performs an evaluation procedure 240 and analyzing procedure 260 which utilizes sensed peripheral responses from the EMG sensors in

order to determine an optimal electrode configuration and/or stimulus parameters; see, for example, paragraphs 0032 - 0036).

With respect to claims 3 and 18, Gliner et al. discloses that the electromyograph includes a plurality of EMG sensors (the electrical signals from the EMG *sensors* are automatically received and processed by the controller; see paragraph 0034).

With respect to claims 4, 19, and 35, Gliner et al. discloses that a sensing procedure is performed after each iteration of the stimulation procedure that involves monitoring a location in the patient for a response to the stimulus applied in the stimulation procedure (see paragraphs 0033-0034). The controller is structured for presenting a map that matches at least one of the individual pairs of subdural electrodes respectively to at least one of the plurality of sensors (the optimization process can terminate by storing the optimized electrode configuration in the memory of the controller, displaying the optimized electrode configuration to a practitioner, or otherwise present the optimized electrode configuration for use; see paragraph 0044).

With respect to claims 5, 21, and 23, Gliner et al. discloses that the controller 130 is operative to minimize individual voltages being applied by the stimulating to the individual pairs of subdural electrodes according to at least one algorithm that pragmatically increases ones of the individual voltages within a predetermined voltage range (stimulating procedure 220 involves several iterations performed by the controller in which the configuration of the electrodes and/or the stimulus parameters can be changed at each iteration; see paragraph 0032. Based upon the pattern of responses,

the analyzing routine 260 incrementally changes one of the stimulus parameters; see for example paragraph 0036).

With respect to claims 6 and 24, the plurality of EMG sensors are necessarily each associated with a respective starting voltage used by the stimulating algorithm in that EMG sensors measure evoked peripheral physiological responses. The applied stimulus for evoking such a response necessarily includes a threshold, starting voltage.

With respect to claims 7 and 25, Gliner et al. discloses an activation threshold determination procedure (see, for example, paragraphs 0058-0059).

With respect to claims 8 and 40, the controller is structured for causing the cortical stimulator to stimulate the individual pairs of the plurality of subdural electrodes in a stimulation pattern (stimulating procedure 220 involves several iterations performed by the controller in which the configuration of the electrodes and/or the stimulus parameters can be changed at each iteration; see paragraph 0032. Gliner et al. discloses various stimulation patterns in paragraphs 0046 with reference to Figures 4A-4C).

With respect to claims 9 and 32, the stimulation pattern includes a sequence of individual stimulation passes, each stimulation pass including a sequence of applying stimuli to the individual pairs, the sequence of applying stimuli including pairing individual ones of the plurality of subdural electrodes according to a predetermined pairing pattern (stimulating procedure 220 involves several iterations performed by the controller in which the configuration of the electrodes and/or the stimulus parameters

can be changed at each iteration; see paragraph 0032. Gliner et al. discloses various stimulation patterns in paragraphs 0046 with reference to Figures 4A-4C).

With respect to claims 10 and 30, the stimulating of individual pairs includes, adjacent electrodes of the grid (see, for example, Fig. 4C).

With respect to claim 11, Gliner et al. discloses that the stimulation procedure may be based on a stimulation minimization algorithm (see, for example, paragraph 0058 which discloses that the optimization procedure seeks to select stimulus parameters that produce the desired neural activity at the lowest level of stimulation).

With respect to claims 12, 26, 31, and 33, Gliner discloses that if the sensed response is within a desired range (which Examiner considers to be verification of prior mapping data), the controller can automatically test the effectiveness of other electrode configurations. In testing other electrode configurations, Examiner considers "the verified electrodes" to necessarily be eliminated from the stimulating procedure/pattern.

With respect to claims 13 and 34, Examiner considers electrode array 110 to be a three-dimensional array because support member 112 is necessarily three-dimensional.

With respect to claims 14 and 20, the controller 130 is structured for creating a stimulation threshold profile for a patient, the profile including a chart of individual stimulation voltages for a plurality of stimulation points, the stimulation voltages each being a minimum voltage for evoking a particular muscle response (the controller analyzes the responses from stimulating procedures 220 to determine a pattern of effectiveness of the corresponding stimulus configurations; see paragraph 0036.

Further, Gliner et al. discloses an activation threshold determination procedure; see paragraphs 0058-0059. Examiner considers “stimulation threshold profile” to encompass the creation of the pattern effectiveness described in Gliner et al.).

With respect to claims 15 and 22, the controller 130 includes an expert system (analyzing procedure 260) for modifying the stimulation pattern (analyzing procedure 260 selects alternate stimulus parameters and/or electrode configurations as described in paragraph 0036).

With respect to claim 16, Gliner et al. discloses that the EMG sensors may be surface, percutaneous, or implanted sensors (see paragraph 0033). Examiner considers “probe” to encompass any device for measuring and/or sensing, and thus considers the EMG sensors as described in Gliner et al. to be “probes.” Further, the sensors are necessarily at least one of monopolar, bipolar, and tripolar.

With respect to claims 27-28, Gliner et al. discloses that the stimulating may include differing stimulus parameters and different electrode configurations (analyzing procedure 260 selects alternate stimulus parameters and/or electrode configurations as described; see paragraphs 0032 and 0036). Applied stimuli may be pulse trains (see paragraph 0027).

With respect to claim 29, Gliner et al. discloses that the polarity of a voltage being applied to one of the pairs of electrodes is reversed for successive stimulations of the one pair (see paragraph 0046; Fig. 4B illustrates a subsequent iteration of the stimulation process in which the polarity of the active electrodes is switched).

With respect to claim 36, Gliner et al. discloses that the optimization method can be utilized to compensate for shifts in the target location (see, for example, paragraph 0040). Examiner considers "determining at least one dimensional offset [from a predetermined map]" to encompass utilizing the optimization method disclosed in Gliner et al. to compensate for shifts in the target location.

With respect to claim 37, Gliner et al. discloses that the optimization procedure may be utilized for various therapies, including restoring motor functions, treating diseases such as epilepsy, and rehabilitating impaired brain functions (see paragraph 0056). Examiner considers "guiding a resectioning of a cortex based on the map" to encompass utilizing the determined optimal stimulation configuration to restore motor functions, treat diseases such as epilepsy, and/or rehabilitate impaired brain functions.

With respect to claim 41, Gliner et al. discloses a method comprising utilizing subdural electrodes (electrode array 110 as described above) as selectable stimulus points (stimulus unit 120 includes a pulse system 140 for generating and sending energy pulses to selectable electrodes of electrode array as described in paragraph 0024) in a closed loop system of cortical mapping based on electromyographic detection events (stimulus unit 120 includes a controller 130 which sends command signals to the pulse system 140 defining the configuration of active electrodes and waveform parameters for the stimulus, and receives signals corresponding to the magnitude of the responses from the sensing device 180 as described in paragraph 0027. The controller associates the reaction with one of the individual pairs of the plurality of subdural electrodes in that the controller performs an evaluation procedure

240 and analyzing procedure 260 which utilizes sensed peripheral responses from EMG sensors in order to determine an optimal electrode configuration and/or stimulus parameters; see, for example, paragraphs 0032 - 0036).

With respect to claim 42, Examiner notes that applicant has invoked 112, 6th paragraph. Examiner considers the means disclosed in Gliner et al. to be equivalent to the means disclosed in the present application. More particularly, Gliner discloses equivalent means for stimulating a portion of a cortex (electrode array 110 operatively connected to a pulse system 140 for generating and sending energy pulses to the electrode array as described in paragraph 0024); equivalent means for detecting a reaction to the stimulating (sensing unit 180 may be an electromyograph for detecting reaction to the stimulating; see, for example, paragraphs 0033-0034); and equivalent means for associating the detecting with the stimulating (a controller 130 which sends command signals to the pulse system 140 defining the configuration of active electrodes and waveform parameters for the stimulus, and receives signals corresponding to the magnitude of the responses from the sensing device 180 as described in paragraph 0027. The controller associates the reaction with one of the individual pairs of the plurality of subdural electrodes in that the controller performs an evaluation procedure 240 and analyzing procedure 260 which utilizes sensed peripheral responses from the EMG sensors in order to determine an optimal electrode configuration and/or stimulus parameters; see, for example, paragraphs 0032 - 0036).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2004/0158298 ("Gliner et al.").

As described above, Gliner et al. discloses a system and method for automatically optimizing stimulus parameters and/or electrode configurations for an implanted electrode array. The system utilizes a sensing deice 180, such as an EMG device, for determining a response in the patient to a stimulus applied to the electrode array (see paragraphs 0026, 0033-0034).

With respect to claims 38-39, Gliner et al. discloses that a sensing procedure is performed after each iteration of the stimulation procedure that involves monitoring a location in the patient for a response to the stimulus applied in the stimulation procedure (see paragraphs 0033-0034). The controller is structured for presenting a map that matches at least one of the individual pairs of subdural electrodes respectively to at least one of the plurality of sensors (the optimization process can terminate by storing the optimized electrode configuration in the memory of the controller, displaying the optimized electrode configuration to a practitioner, or otherwise present the optimized electrode configuration for use; see paragraph 0044). Gliner et al. fails to specifically disclose that displaying the optimized electrode configuration to a practitioner may

include displaying a relationship between the data set of EMG measurements and a scaled graphical image or a stored map profile of a cortex. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the display of Gliner et al. to display a relationship between the data set of EMG measurements and a scaled graphical image or a stored map profile of a cortex in order to provide the practitioner with a visual representation of the relationship between the selected electrode configuration and the corresponding stimulation site on the cortex.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent No. 6,959,215 teaches a method for treating essential tremor that includes applying electrical stimulation to a stimulation site a plurality of subdural electrodes formed in a grid.

U.S. Patent Application Publication 2004/0019370 teaches a method and system for determining a neural stimulation threshold for a patient including an electrode array, a pulse system, a sensing unit such as an EMG device, and a controller.

U.S. Patent No. 6,091,979 teaches a subdural electrode array for monitoring cortical activity. After obtaining sufficient recordings, cortical stimulations and mapping of somatosensory areas by evoked potentials can be performed utilizing the implanted, subdural electrode array (see col. 6, lines 28-50).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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George Manuel
Primary Examiner